REMARKS / ARGUMENTS

I. Amendments to the specification and formal matters

The claims page have been amended to begin with "What is claimed is:", as required by the Examiner.

Page 7 of the specification has been amended to delete reference at line 29 to the web address "http://chlamydia-www.berkeley.edu:4231/", as required by the Examiner.

Page 22 has been amended to provide an updated address for the American Type Culture Collection at line 5.

The Examiner has stated that pages 7a and 8 are not coherently joined. The text on these pages in fact do read continuously and coherently.

The Examples have been amended at page 48, line 17, and page 49, line 10, to identify sequences specifically by SEQ ID NOs. It is clear that SEQ ID NO:1 encodes the ATP/ADP translocase expressed from plasmid construct pCAI764.

The application as originally filed (PCT/CA99/01224) does contain an Abstract. The Abstract has been amended for further clarity.

Amended Figures 1 to 4 have been submitted. The Figure labels have been corrected at Figures 1 and 2. Figure 4 has been re-sized as to be within the acceptable margins. The numbers, characters and legends in replacement Figures 1 to 4 are now plain and legible.

II. Claim amendments

Claims 44-85 remain pending in this application. Claims 44, 46-50, 63-78, 80-82, 84 and 85 are withdrawn.

Claims 86 and 87 have been added. Claim 86 is derived from part (c) of claim 45; claim 87 is derived from part (iii) of claim 51. Since these claims are drawn to subject matter originally present in elected claims 45 and 51, the Examiner is respectfully requested to enter and examine claims 86 and 87.

Claims 45, 51, 52, 56-59, 61, 62, 79 and 83 have been amended to more clearly and particularly claim the invention, as described in more detail below. Corresponding amendments have been made to the withdrawn claims. Because these amendments do not introduce new matter, entry thereof by the Examiner is respectfully requested.

Applicant retains the right to present the withdrawn claims, and claims drawn to the cancelled subject matter, in a divisional application(s).

Claim 45 has been amended to recite --An isolated nucleic acid--. Claims 61 and 62 have been amended to recite --An isolated and purified (probe / primer)--. Basis for the amendments is found at least at the paragraph beginning at line 28 of page 10.

Claims 45, 51, 61 and 62 have also been amended to remove reference to fragments (as defined with respect to SEQ ID NO:1) and variants. Claims 45 and 51 have also been amended to define the polypeptide encoded by SEQ ID NO:1 as SEQ ID NO:2. Claims 61 and 62 have also been amended to remove reference to antisense sequences.

Claim 58 has been amended to depend on elected claim 45.

Claim 59 has been re-written as an independent claim. As amended, the claim is drawn to a composition comprising a nucleic acid and a carrier or diluent.

Claims 51, 52 and 79 have been further amended to state --wherein the vaccine vector comprises ... nucleic acid--. Basis for this amendment is found at least

at line 33 of page 24 to line 2 of page 25; lines 22-23 and 29-31 of page 25; lines 21-34 of page 26; and lines 10-32 of page 27.

Claims 52 and 79 have been amended to define the open reading frame as that of SEQ ID NO:2.

Claim 83 has been amended to depend on elected claim 51.

Because the foregoing claims do not introduce new matter, entry thereof by the Examiner is respectfully requested.

III. Double patenting

The Examiner has provisionally rejected claims 45, 51-62 79 and 83 under the doctrine of obviousness-type double patenting over the claims of US 09/892,851. US 09/892,851 has been abandoned, thus rendering moot this ground for rejection.

IV. Rejection Under 35 U.S.C. § 101

The Examiner has rejected claim 45 under 35 U.S.C. 101 as being drawn to non-statutory subject matter. Applicants traverse this ground for rejection.

Claim 45 has been amended to recite --An isolated nucleic acid molecule--, as suggested by the Examiner. Withdrawal of the rejection under 35 U.S.C. 101 is respectfully requested.

V. Rejection of Claim 83 Under 35 U.S.C. § 112, First Paragraph

The Examiner has rejected claim 83 under 35 U.S.C. 112, first paragraph, alleging that the specification lacks complete information for making plasmid pCAI764 and that it fails to teach that SEQ ID NO:1, which encodes SEQ ID NO:2, has been cloned as expression plasmid pCAI764. Applicants traverse this ground for rejection.

The Examples have been amended to identify sequences specifically by SEQ ID NOs. It is clear that SEQ ID NO:1 encodes the ATP/ADP translocase expressed

from plasmid construct pCAI764. The specification describes the complete sequence of the ATP/ADP translocase gene and the restriction sites flanking it, the restriction sites used to clone the gene into the construct, and the source of all materials used to prepare the construct (Examples 1, 2 and Figures 1-3). Given this information, a skilled person is readily able to reproduce plasmid pCAI764, as well as other expression vectors expressing the polypeptide of SEQ ID NO:2, fragments and variants thereof.

Applicants believe that the specification as amended contains sufficient written description of and is fully enabling for the subject matter of claim 83, and that no biological deposit is required. Withdrawal of the rejection of claim 83 under 35 U.S.C. 112, first paragraph, is respectfully requested.

VI. Rejection Under 35 U.S.C. § 112, First Paragraph (Written Description)

Claims 45, 51-62, 79 and 83 of record stand rejected under 35 USC § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicants respectfully traverse these rejections and submit that the claims, as presently amended, fully comply with the written description requirement.

The instant application describes polynucleotides encoding SEQ ID NO: 2 and provide their use for eliciting an immune response. Applicants respectfully submit that the specification further provides a full written description concerning the use of nucleic acid molecules having at least 38 or 60 consecutive nucleotides from SEQ ID NO:1, or encoding a fragment of at least 12 amino acids of SEQ ID NO: 2, or amino acid sequences possessing at least 75% or 80% identity to SEQ ID NO:2.

Applicants respectfully submit that the nucleic acid molecules of claims 45, 51-62, 79 and 83 of record are defined in clear structural terms, and not solely in functional terms. The instant specification specifically recite fragments of SEQ ID NO:2 of at least 12 amino acids in length (page 17, lines 9-14). SEQ ID NO:2 is 515

amino acid residues in length. The skilled person can immediately envisage every 12-amino acid fragment of SEQ ID NO:2 based on the specification as filed. Thus, there is no question that the specification as filed provides a written description of the claimed fragments.

Independent claims 45, 51, 52, 61 and 62 of record recite polypeptides possessing at least 75% or 80% identity to SEQ ID NO: 2. The specification provides explicit details for calculating sequence identity and for identifying sequences having a specified degree of sequence identity to SEQ ID NO:2 (see e.g. page 12, lines 21-30 and page 13, line 32 to page 16, line 8). Applicants respectfully submit that, given the explicit disclosure in the specification of SEQ ID NO:2 and the significant degree of amino acid sequence identity recited, claims 45, 51-62, 79 and 83 of record define the invention in such clear, precise, and exact terms as to satisfy the written description requirement.

The Examiner states at page 12 of the Office Action that the specification fails to teach a single variant or homolog of a polypeptide sequence encoded by SEQ ID NO:1. Applicants respectfully disagree. As indicated above, the specification does give explicit details for calculating sequence identity, thereby teaching sequences possessing at least 75% or 80% identity to SEQ ID NO:2.

The Examiner states at page 12 of the Office Action that the claimed polynucleotides do not exist as an invention "independent of their function in encoding a putative outer membrane protein". Since SEQ ID NO:1 encodes an ATP/ADP translocase (see page 8, lines 23-24), we assume the Examiner's reference to a 98 kD outer membrane protein is an error. In any case, Applicants submit that the claimed polynucleotides do exist as an invention independent of their function in encoding an ATP/ADP translocase. At least part of their utility lies in encoding polypeptides which elicit an immunogenic response. A 12-amino acid or larger fragment of a polypeptide, or a variant polypeptide, can elicit an immunogenic response without having retained the putative translocase function of the original sequence (see argument regarding 35 U.S.C. §112, First Paragraph enablement, below).

The Examiner states at page 12 of the Office Action that "the 98kD outer membrane protein (*sic*) is uncharacterized by this specification and is not asserted to belong to any known family of proteins". The Examiner then goes on to state that there must be some nexus between the structure of a gene sequence and the structure of the protein encodes, and the function of that encoded protein, and that similar function cannot be predicted from the modification of the gene.

With respect, whether the specification characterizes the proteins as 98kD outer membrane proteins or as ATP/ADP translocases is irrelevant. The claims do not recite outer membrane protein function. The explicit function of the claimed sequences lies in eliciting an immunogenic response (see the argument regarding 35 U.S.C. §112, First Paragraph enablement, below).

The Examiner further states at page 13 of the Office Action that "the specification fails to teach the structure or relevant identifying characteristics of a representative number of polynucleotides encoding a representative number of 98kD outer membrane polypeptides (*sic*)", sufficient to allow a skilled person to determine the inventors' possession of the invention.

Applicants respectfully disagree. The principle of a "representative number of species" was established in *University of California v. Eli Lilly and Company*, 43 USPQ 2d 1398 (Fed. Cir. 1997). Applicants respectfully submit that the *Eli Lilly* decision is inapplicable to the facts of the instant application. In *Eli Lilly*, the court held that disclosure of rat insulin-encoding cDNA does not provide adequate written description of claims generically reciting cDNA encoding vertebrate insulin and mammalian insulin. The single species of vertebrate or mammalian cDNA disclosed did not describe the entire genus of vertebrate or mammalian cDNAs claimed. The instant case is different. Applicants claim a nucleic acid molecule encoding a polypeptide defined by a specific amino acid sequence, fragment length, and sequences having a significant degree of sequence identity thereto. The amino acid sequence, variants and fragments thereof are precisely defined in the instant claims. This is not an instance of a single species being presented to support the entirety of a genus.

In *Eli Lilly*, the Court stated, at page 1406:

> In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus. In claims to genetic material, however, a generic statement such as 'vertebrate insulin cDNA' or 'mammalian insulin cDNA' without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.

Applicants respectfully submit that the instant claims define the invention using structural language similar to that of a generic chemical formulae (i.e. by reference to a specific amino acid sequence), a practice cited with approval in *Eli Lilly*. The claims do not merely recite a generic name or functional definition such as "vertebrate insulin cDNA" as in the *Eli Lilly* case. Rather, the skilled person can readily distinguish the formulae of the instant claims from other formulae and can immediately identify and envisage many of the species that the instant claims encompass.

The Examiner further comments that conception cannot be achieved until reduction to practice has occurred, and cites a number of cases, including *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.* 18 USPQ 2d 1016, 1021 (Fed. Cir. 1991). In *Amgen*, the Court held that "conception of a generalized approach for screening a DNA library that might be used to identify and clone the EPO gene of then unknown constitution is not conception of a 'purified and isolated DNA sequence' encoding human DNA".

The instant application and claims are distinguishable from *Amgen*. The claims recite a specific amino acid sequence and variants having significant identity. This is not an instance of defining a chemical compound by name only and hoped-for function as in *Eli Lilly*, or the mere elucidation of a research plan to obtain a chemical

compound described by name only as in *Amgen*. Instead, Applicants' claims recite specific amino acid sequences and clearly defined fragments and variants thereof.

For the foregoing reasons, Applicants respectfully submit that the specification provides a complete written description of the claims of record. Solely to advance prosecution, the claims have been amended to remove reference to variants and fragments, the latter as defined in relation of SEQ ID NO:1. Applicants retain the right to present claims drawn to the cancelled subject matter in a divisional application(s).

Reconsideration and withdrawal of the rejections of the claims as lacking written description are respectfully requested.

VII. Rejection Under 35 U.S.C. § 112, First Paragraph

The Examiner has rejected claims 45, 51-62, 79 and 83 under 35 U.S.C. 112, first paragraph, alleging lack of enablement on a number of grounds. Applicants traverse the grounds for rejection as follows.

1. Fragments are enabled

The Examiner states at page 14 of the Office Action that the specification is not enabling for nucleic acids, vaccines or compositions comprising a nucleic acid encoding immunogenic fragments of at least 12 amino acid in length from SEQ ID NO:2, or at least 38 or 60 consecutive nucleotides from SEQ ID NO:1. Applicants traverse this ground for rejection.

With respect to vaccines and compositions, Applicants point out that any peptide comprising at least 12 consecutive amino acids from SEQ ID No:2, or encoded by at least 38 or 60 consecutive nucleotides from SEQ ID NO:1 in the reading frame set forth in SEQ ID NO:2, would work to some extent as an immunogenic fragment. As stated at page 16 line 30 to page 17 line 8 of the specification:

> "It is an accepted practice in the field of immunology to use fragments and variants of protein immunogens as vaccines, as all

that is required to induce an immune response to a protein is a small (*e.g.*, 8 to 10 amino acid) immunogenic region of the protein. Various short synthetic peptides corresponding to surface-exposed antigens of pathogens other than *Chlamydia* have been shown to be effective vaccine antigens against their respective pathogens, *e.g.* an 11 residue peptide of murine mammary tumor virus (Casey & Davidson, Nucl. Acid Res. (1977) 4:1539), a 16-residue peptide of Semliki Forest virus (Snijders *et al.*, 1991. J. Gen. Virol. 72:557-565), and two overlapping peptides of 15 residues each from canine parvovirus (Langeveld *et al.*, Vaccine 12(15):1473-1480, 1994)."

Applicants further submit that it is a matter of routine in the art to generate an immune response to peptides of 6 to 15 amino acids, as is evident by the number of groups offering to produce anti-peptide antibodies as a commercial service. The various Web sites include the following:

(1) The article: Protocol: "Making antibodies to synthetic peptides" is at: http://medicine.ucsd.edu/hypertension/protocol_making_antibodies_to_synthetic_peptides.htm

(2) The article "How to make peptide antibody a success..." is at: http://www.eurogentec.com/upload/summer_2001/how_to_make.pdf

(3) The flowchart "At a glance: Peptide-antibody production..." is at: http://www.eurogentec.be/upload/documentation/Protein_services/prot_serv_glan_uk.pdf

(4) A listing of suppliers of Peptide antibody production is at: http://www.biosupplynet.com/cfdocs/products/prod_supp.cfm?prod_id=2255

(5) The page titled "Peptide antibodies" is at: http://www.phoenixpeptide.com/pep_antibodies.html

(6) The page titled "Anti-Peptide Antibody programs" is at: http://www.crpinc.com/services/index.html

(7) The page titled "Peptides" is at: http://www.qualbio.com/peptides.htm

(8) The page titled "Anti-Peptide" is at: http://www.qualbio.com/anti-pep.htm

(9) The page titled "Custom Immunology Services" is at: http://www.bioreagents.com/index.cfm/fuseaction/pages.show/name/General_Promo

(10) The page titled "Polyclonal Antibody production" is at: http://www.crpinc.com/services/poly.html

The Examiner will note in particular the protocol from "http://medicine.ucsd.edu" (enclosed) which states that by using the described protocol, which is a routine protocol, synthetic peptide antibodies which recognize the antigen (intact full length molecule, from which the peptide was derived) can be obtained, and that although the antibodies may be of low titer, a usable antibody always result.

In view of the above, Applicants submit that the specification is enabling for nucleic acids, vaccines or compositions comprising a nucleic acid encoding immunogenic fragments of at least 12 amino acid in length from SEQ ID NO:2, or at least 38 or 60 consecutive nucleotides from SEQ ID NO:1.

2. Variants are enabled

The Examiner states at page 14 of the Office Action that the specification is not enabling for vaccines or compositions comprising nucleic acids encoding polypeptides which are at least 75% or 80% identical to the polypeptide encoded by SEQ ID NO:1. In the paragraph bridging pages 15 and 16 of the Office Action, the Examiner has further questioned whether the variants would have any function with respect to immunoprotection. Applicants traverse this ground for rejection.

The Examiner states at page 16 of the Office Action that the extent of identity of SEQ ID NO:2 to known myosin proteins (presumably "ATP/ADP translocase" is intended) is not disclosed in the specification. Applicants point out that homology to known ATP/ADP translocases is not relevant to vaccine use of the variants as defined in the claims.

What is relevant is whether the claimed variants would induce an immuno-protective response. This is addressed at page 13, lines 18-31 of the specification:

> "Allelic variants are very common in nature. For example, a bacterial species such as *C. pneumoniae,* is usually represented by a variety of strains that differ from each other by minor allelic variations. Indeed, a polypeptide that fulfills the same biological

> function in different strains can have an amino acid sequence (and polynucleotide sequence) that is not identical in each of the strains. Despite this variation, an immune response directed generally against many allelic variants has been demonstrated. In studies of the *Chlamydial* MOMP antigen, cross-strain antibody binding plus neutralization of infectivity occurs despite amino acid sequence variation of MOMP from strain to strain, indicating that the MOMP, when used as an immunogen, is tolerant of amino acid variations."

Thus, once it has been determined that a particular protein is immunoprotective, a skilled person would expect that minor variations of at most 20% or 25% of the amino acid positions, would also work because such modifications are not expected to substantially alter immunogenicity.

Applicants further point out that testing for retention of immunogenicity is routine and is described in detail throughout the specification. It is well known in the art that similarity/homology in amino acid sequences can be relied upon to determine conservation of function of DNA sequences. The specification does contain sufficient teaching for making and using the polypeptides, conservatively modified or unmodified, without requiring undue experimentation. Applicants submit that the specification is enabling for vaccine vectors comprising a nucleic acid encoding fragments or variants which are at least 75% or 80% identical to SEQ ID NO:2.

In view of the above, Applicants submit that the specification is enabling for vaccines or compositions comprising a nucleic acid encoding variants which are at least 75% identical to the polypeptide encoded by SEQ ID NO:1 and which have been modified by conservative amino acid substitution without loss of immunogenicity. Solely to advance prosecution, the claims have been amended to remove reference to variants. Applicants retain the right to present claims drawn to the cancelled subject matter in a divisional application(s).

3. Fusions are enabled

The Examiner states at page 14 of the Office Action that the specification is not enabling for vaccines comprising a nucleic acid encoding a fusion protein. Applicants traverse this ground for rejection.

Fusion proteins of the invention, and how to make and use them, are described in detail at page 19, line 15, to page 21, line 2. There, N- or C-terminal fusions with peptide tails are described. A method of making such fusion by using an in-frame fusion, *i.e.*, a hybrid gene, is described, as well as an alternative method where the polynucleotide sequence encoding the polypeptide or polypeptide derivative is inserted into an expression vector in which the polynucleotide encoding the peptide tail is already present. Commercial sources of such vectors and instructions for their use are described (*e.g.* the pMal-c2 or pMal-p2 system from New England Biolabs, in which the peptide tail is a maltose binding protein, the glutathione-S-transferase system of Pharmacia, or the His-Tag system available from Novagen).

The specification then goes on to describe fusions to heterologous signal peptides, or to polypeptides having adjuvant activity, such as subunit B of either cholera toxin or *E. coli* heat-labile toxin, or fusions to strong T-cell epitopes or B-cell epitopes (*e.g.* the Hepatitis B virus core antigen, D.R. Millich et al., "Antibody production to the nucleocapsid and envelope of the Hepatitis B virus primed by a single synthetic T cell site", Nature. 1987. 329:547-549, or an epitope which has been identified based on computer-assisted analysis of probable T- or B-cell epitopes). The specification then describes how to effect fusion, i.e. by the polypeptide of the invention fused to the N- or to the C-terminal end of the polypeptide having adjuvant activity or T- or B-cell epitope, or inserted internally within the amino acid sequence of the polypeptide having adjuvant activity.

In view of the above, Applicants submit that the specification is enabling for vaccines comprising a nucleic acid encoding a fusion protein, as recited in claims 43-45.

In view of the above arguments and amendments, Applicants submit that claims 45, 51-62, 79 and 83, as well as new claims 86 and 87, are enabled. Withdrawal of the rejection under 35 U.S.C. 112, first paragraph, is respectfully requested.

VIII. Rejection Under 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected claims 45, 51-62, 79 and 83 under 35 U.S.C. 112, second paragraph. Applicants traverse the grounds for rejection as follows.

The Examiner has rejected claims 45, 51, 52 and 79, stating that the metes and bounds of the claimed nucleic acid is unclear. Claims 45 and 51 have been amended to refer to a sequence encoding SEQ ID NO:2 which explicitly defines the reading frame. Claims 52 and 79 have been amended to define the open reading frame as that set forth in SEQ ID NO:2.

The Examiner has alleged that claims 51 and 52 are vague and indefinite with respect to the "first" and "second" nucleic acids, and "vaccine vector and at least one first nucleotide molecule". Claim 51 has been re-written to recite --A vaccine comprising a vaccine vector wherein the vaccine vector comprises a polypeptide-encoding nucleic acid sequence--. Claim 52 has been re-written to recite --A vaccine comprising a vaccine vector wherein the vaccine vector comprises a nucleic acid encoding a fusion protein--.

The Examiner has alleged that there is insufficient antecedent basis in claims 51 and 52 for "each first nucleic acid". This expression no longer appears in amended in claims 51 and 52.

The Examiner has alleged that claim 57 is vague with respect to the "additional Chlamydia polypeptide". As is clear from amended claim 57, which ultimately depends on claim 51, the additional polypeptide is from Chlamydia and enhances the immune response to the polypeptide originally recited in claim 51.

The Examiner has alleged that claim 59 is vague and confusing. Claim 59 has been re-worded so that the claim is drawn to a vaccine which comprises a nucleic acid molecule, and pharmaceutically acceptable carrier or diluent suitable for use in a vaccine.

In view of the above arguments and amendments, Applicants believe that the metes and bounds of claims 45, 51-62, 79 and 83, as amended, can be clearly determined and the claims are clearly defined. Withdrawal of the rejection under 35 U.S.C. 112, second paragraph, is respectfully requested.

IX. Rejection Under 35 U.S.C. § 102(a) and 35 U.S.C. § 102(b)

1. Kalman et al. (Accession No. AE001619 & Nat. Genet. 1999, 21(4):385-389)

The Examiner has rejected claims 45 and 51-62 under 35 U.S.C 102(a) as being anticipated by Kalman et al. Applicants traverse this ground for rejection.

With respect to claim 45, the claim has been amended to recite --An isolated nucleic acid molecule comprising: (a) SEQ ID No: 1; or (b) a sequence encoding SEQ ID No: 2--. As indicated by the Examiner's sequence comparison, Kalman's sequence is different from SEQ ID NO:1 (at least at nucleotide positions 895 and 921).

Kalman et al. does not disclose the vaccines and pharmaceutical compositions of the instant application. The examiner fails to point where in Kalman it is stated that these proteins were produced recombinantly. Kalman have sequenced the entire genome of two Chlamydia strains by cloning random fragments into a M13 vector for automated sequencing, no expression data is shown. Kalman does not disclose or suggest expressing sequences. Therefore, Kalman's sequences lack the structural feature of being operatively linked to one or more control sequences for expression of the polypeptide, as specified in the claims. Since Kalman's sequences are not in expressible form and are not capable of performing the intended use, Kalman et al does not anticipate the vaccines and compositions of the present application.

2. Commercial catalogs

The Examiner has rejected claims 61 and 62 under 35 U.S.C. § 102(b) as being anticipated by a number of commercial catalogs disclosing random primers, probes and linkers. Applicants traverse this ground for rejection.

The claims have been amended to recite "An isolated and purified" probe or primer. The cited references disclose random primer or probe mixes, in which any particular probe or primer is, by definition, not isolated and purified.

None of the cited references disclose all elements of the claims. That is, none of the cited references disclose a purified probe of 5 to 100 nucleotides which hybridizes under stringent conditions to SEQ ID No: 1, or to a complementary sequence of SEQ ID No:1; or disclose a purified primer of 10 to 40 nucleotides which hybridizes under stringent conditions to SEQ ID No: 1, or to a complementary sequence of SEQ ID No:1. In fact, none of the cited references explicitly disclose any sequence that can be compared with the sequences of claims 61 and 62.

If it is the Examiner's intention to reject claims 61 and 62 as being inherently anticipated by the random primer mixes and linkers and kits, Applicants point out that a mere possibility of the primer and probe of claims 61 and 62 having been present in purified form would not constitute inherent anticipation (*Continental Can Company USA, Inc. v. Monsanto Company*, 948 F.2d 1264, 20 USPQ2d 1746 (Fed. Cir. 1991)).

In view of the above, withdrawal of the rejection of claims 61 and 62 under 35 U.S.C§102(b) is respectfully requested.

3. Griffais (Accession No. AAY34951 & WO 9927105)

The Examiner has rejected claims 45 and 51-62 under 35 U.S.C 102(a) as being anticipated by Griffais. Applicants traverse this ground for rejection.

With respect to claim 45, the claim has been amended to recite --An isolated nucleic acid molecule comprising: (a) SEQ ID No: 1; or (b) a sequence encoding SEQ ID No: 2--. As indicated by the Examiner's sequence comparison, Griffais' sequence is different from SEQ ID NO:1 (at least at nucleotide positions 895 and 921).

Griffais describes the sequence of 1296 distinct, putative open reading frames (ORFs) of *Chlamydia pneumoniae*. The sequences of the 1296 ORFs are diverse.

None of the sequences were expressed. Griffais then speculates that any of the 1296 ORFs would be useful as a vaccine.

The Griffais reference does not provide any guidance as to which of the 1296 ORFs are actually useful as vaccines. The skilled person could not reasonably be expected to pick through the various and diverse teachings of Griffais to arrive at the conclusion that SEQ ID NO:1 encoding the ADP/ATP translocase of the instant application, encodes an immunoprotective antigen. Without further guidance, the skilled person would be at a loss to determine, as amongst the 1296 ORFs recited, which if any could realistically be used to formulate a vaccine.

Applicants respectfully submit that the 1296 sequences described in Griffais are not sufficiently limited or well delineated to anticipate the present claims. One of ordinary skill in the art could not be able to "at once envisage" the specific combination of SEQ ID NO:1 encoding ADP/ATP translocase with immunoprotectiveness, as presently claimed, and as required for a finding of anticipation. See *Ex parte A*, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990).The recitation in Griffais of a vast number of ORFs does not "describe" and therefore does not anticipate the immunoprotective compositions presently claimed. See *In re Petering*, 301 F.2d 676, 133 USPQ 275 (CCPA 1962).

In other words, the skilled person, confronted with the Griffais reference, could not "see the trees for the forest" in view of the large number of diverse ORFs recited in the reference. Applicant submits that such a disclosure does not constitute anticipation. See *Fujikawa v. Wattanasin* (39 USPQ2d 1895), quoting in part from *In re Ruschig* (154 USPQ 118):

> It is an old custom in the woods to mark trails by making blazemarks on the trees. It is no help in finding a trail ... to be confronted simply by a large number of unmarked trees. Appellants are pointing to trees. We are looking for blaze marks which single out particular trees. We see none.

Withdrawal of the rejection under 35 U.S.C. 102(a) is respectfully requested.

X. Concluding Remarks

In view of the above amendments and remarks, reconsideration and favorable action on all pending claims are respectfully requested. If any questions or issues remain, the Examiner is invited to contact the undersigned at the telephone number set forth below so that a prompt disposition of this application can be achieved.

The Petition for Extension of Time pursuant to 37 CFR 1.136 and the fee are being submitted concurrently with this Response. If a fee is required for an extension of time which is not accounted for above, such an extension is requested and the U.S.P.T.O. is authorized to withdraw from our Deposit Account Number 19-0741 any fee required.

Respectfully submitted,

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